UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

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ANNA CRISSI,

Plaintiff,

-against-

JOHNSON & JOHNSON VISION CARE, INC. and COSTCO WHOLESALE CORPORATION,

Defendants.

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MEMORANDUM & ORDER
15-CV-4230 (ENV)(SMG)

Vitaliano, D.J.

On June 11, 2015, plaintiff Anna Crissi filed this action in Supreme Court, Kings County, against defendants Johnson & Johnson Vision Care, Inc. ("Johnson & Johnson") and Costco Wholesale Corporation ("Costco"), alleging negligence, strict liability and breach of the warranties of merchantability and fitness. On July 20, 2015, Johnson & Johnson timely removed that action to this Court on diversity grounds then, on July 27, 2015, filed its answer. It now moves, pursuant to Rule 12(c), for judgment on the pleadings. For the reasons that follow, the motion is granted and the complaint is dismissed.[1]

Background

Facts are drawn from the complaint and other materials referenced in it. See Chambers v. Time Warner, Inc., 282 F.3d 147, 153 (2d Cir. 2002). All factual statements alleged in the plaintiff's pleadings are taken as true and all reasonable inferences are drawn in her favor. Vietnam Ass'n for Victims of Agent Orange v. Dow Chem. Co., 517 F.3d 104, 115 (2d Cir. 2008).

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[1] Costco, which consented to removal, see Dkt. No. 1, and filed its own timely answer to the complaint, see Dkt. No. 7, has moved to join in Johnson & Johnson's motion, see Dkt. No. 17. That motion is granted.

On or about July 14, 2013, Crissi purchased a box of Johnson & Johnson's "Acuvue Oasys" extended wear contact lenses from the Costco store at 605 Rockaway Turnpike, Lawrence, New York. Compl., Dkt. No. 1, ¶ 19. They did not, she claims, function as promised. Rather, after placing one of the lenses onto her right eye, she suffered what she describes as "irreparable damage" in the form of "permanent corneal scarring." Id. ¶¶ 20-21. Crissi places the blame for this injury squarely on the contact lenses made by one defendant and sold by the other, maintaining that she used the contact lenses in the intended and foreseeable manner. Id. ¶¶ 40, 49-51, 82. She brings the full roster of claims typical of products liability cases. See id. ¶¶ 1-67.

Standard of Review

In deciding a motion for judgment on the pleadings under Rule 12(c), district courts use the same standards as are applicable to motions brought under Rule 12(b)(6). Hayden v. Paterson, 594 F.3d 150, 160 (2d Cir. 2010). In other words, the test remains whether the complaint has complied with Rule 8(a)(2)'s requirement of providing a "short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). This rule does not compel a litigant to supply "detailed factual allegations" in support of her claims, Bell Atlantic Corp. v. Twombly, 550 U.S. 544, 555, 127 S. Ct. 1955, 1964 (2007), "but it demands more than an unadorned, the-defendant-unlawfully-harmed-me accusation." Ashcroft v. Iqbal, 556 U.S. 662, 678, 129 S. Ct. 1937, 1949, 173 L. Ed. 2d 868 (2009). "A pleading that offers 'labels and conclusions' . . . will not do." Id. (quoting Twombly, 550 U.S. at 555); see also In re NYSE Specialists Sec. Litig., 503 F.3d 89, 95 (2d Cir. 2007). "Nor does a complaint suffice if it tenders 'naked assertion[s]' devoid of 'further factual enhancement.'" Iqbal, 556 U.S. at 678 (quoting Twombly, 550 U.S. at 557).

Thus, to survive a Rule 12(c) motion, the complaint "must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" Iqbal, 556 U.S. at 663 (quoting Twombly, 550 U.S. at 570). This "plausibility standard is not akin to a probability requirement, but it asks for more than a sheer possibility that a defendant has acted unlawfully." Iqbal, 556 U.S. at 678 (citation and internal quotations omitted).

Discussion

The 1976 Medical Device Amendments ("MDAs") to the Food, Drug, & Cosmetic Act preempt all state law claims relating to safety or effectiveness of a medical device that "is different from, or in addition to, any Federal requirement." 21 U.S.C. § 360k(a). Under Supreme Court precedent, this clause expressly preempts all state law tort and warranty claims relating to FDA-approved Class III medical devices, like the Johnson & Johnson contact lenses at issue here, because of the "rigorous regime" surrounding the premarket approval ("PMA") process and the deference owed the FDA. Riegel v. Medtronic, Inc., 552 U.S. 312, 317–26, 128 S. Ct. 999, 1003–09, 169 L. Ed. 2d 892 (2008) (holding that the FDA's review regime "*is* federal safety review" and that, accordingly, "remove[s] all means of judicial recourse") (emphasis in original) (citation omitted). As articulated by the Supreme Court, preemption is determined by reviewing whether the FDA has established requirements specific to the device and, then, whether the state law claim would impose requirements that "relate to safety and effectiveness" that are "different from, or in addition to" the federal requirements. 21 U.S.C. § 360k(a); Riegel, 552 U.S. at 321-23. If both inquiries can be answered in the affirmative, the claim is preempted.

As a corollary, to survive preemption, claims must set forth a specific problem with or violation of federal law, be specific to the subject device and link that violation to the alleged injury. See Burkett v. Smith & Nephew GmbH, No. CV 12-4895, 2014 WL 1315315, at *4-7

(E.D.N.Y. Mar. 31, 2014) (dismissing claim on preemption grounds for failure to link alleged violation to injury); Ilarraza v. Medtronic, Inc., 677 F. Supp. 2d 582, 588-89 (E.D.N.Y. 2009) (dismissing claim as preempted because plaintiff could not show alleged manufacturing violation was linked to injury); Horowitz v. Stryker Corp., 613 F. Supp. 2d 271, 280 (E.D.N.Y. 2009) (dismissing claim where plaintiff failed to establish necessary link between purported violations of law and plaintiff's cause of action).[2]

Bathed in this light, Crissi's lawsuit cannot withstand preemption. It is undisputed that the contact lenses she purchased and used are a Class III medical device that has passed through the PMA process and, as a result, are subject to the MDA. As to the second critical inquiry, it is also self-evident that Crissi is relying on common law duties, as recognized in state law, in an attempt to enforce safety standards that would enlarge upon the PMA process which found the lenses sufficiently safe for their intended purpose. Thus, following the course charted by the Supreme Court, each of plaintiff's claims cannot survive. See Riegel, 552 U.S. at 325 ("[E]xcluding common-law duties from the scope of pre-emption would make little sense.").

Nor can Crissi's claims in their recapitulated style – for design defect, manufacturing defect, or failure to warn – survive preemption. Not only does plaintiff fail to identify any specific design flaw in the subject contact lenses, but, more importantly for preemption purposes, she does not claim that the design as implemented deviated in any way "from the design approved by the FDA." See Burkett, 2014 WL 1315315, at *4 (dismissing design defect claim for failure to state any deviation from approved design); Simon v. Smith & Nephew, Inc., 990 F.

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[2] The only exceptions to this rule are the so-called "parallel" actions, which are state court actions alleging injuries caused by a federal regulation specific to the medical device alleged to have caused injury. Ilarraza, 677 F. Supp. 2d at 585-86. Crissi's claims plainly fail to fit this niche because "no regulation [she has] relied upon refers specifically to the medical device at issue . . . ." Id. at 588.

Supp. 2d 395, 405 (S.D.N.Y. 2013) (dismissing as preempted design defect claims regarding PMA-approved device for failure to identify design flaw). In similar fashion, Crissi again fails to allege a violation of the federal manufacturing requirements specific to the contact lenses she claims injured her. Moreover, she does not even claim, let alone plausibly state facts to show, any link between her injuries and a defect resulting from a manufacturing defect, improper workmanship or defective materials in the production and sale of a product that, resultingly, did not comply with FDA regulations. See Burkett, 2014 WL 1315315, at *4-5 (dismissing manufacturing defect claim for failing to allege flawed manufacturing, improper workmanship, or defective materials specific to device at issue); Horowitz, 613 F. Supp. 2d at 283-84 (dismissing manufacturing defect claim for failure to identify specific ways in which manufacturer violated federal requirements). As for the last straw, all of the promotional materials that Crissi could have relied on were pre-approved by the FDA, see Def. Br., Dkt. No. 14, at 3-5; PMA Confirmation, Dkt. No. 14-6. Plaintiff does not plausibly plead facts supporting a claim that Johnson & Johnson "modified or failed to include [these] labels and warnings that the FDA approved . . . ." Cordova v. Smith & Nephew, Inc., No. 14-CV-351, 2014 WL 3749421, at *7 (E.D.N.Y. July 30, 2014). Indeed, she does not even advance such a claim. Accordingly, none of these causes of action can survive preemption.[3]

In sum, Crissi has failed to plead any facts showing that her injuries resulted from Johnson & Johnson's deviation, in any way, from the rigorous federal testing and strict approval

[3] With these claims clearly preempted, Crissi's derivative claims are, by necessity, preempted as well, see Franzese v. St. Jude. Medical, Inc., No. CV 13-3203, 2014 WL 2863087, at *8 (E.D.N.Y. June 23, 2014); Horowitz, 613 F. Supp. 2d at 284-86; moreover, these claims suffer from the same deficiencies and would, in any event, be preempted on their own, see Burkett, 2014 WL 1315315, at *7.

process covering lenses, nor has she plausibly pleaded any facts showing responsibility on the part of Costco. Accordingly, all of her claims are dismissed as preempted.

Conclusion

For the foregoing reasons, defendants' motion for judgment on the pleadings is granted. The complaint is dismissed.

The Clerk of Court is directed to enter judgment accordingly and to close this case.

So Ordered.

Dated: Brooklyn, New York
August 22, 2016

/s/ USDJ ERIC N. VITALIANO

ERIC N. VITALIANO
United States District Judge